

Remarks

Rejection under 35 USC §112 first paragraph

Claims 1-6, and 9-19 are rejected under 35 USC §112, first paragraph for lack of written description. Specifically, the Examiner states that the specification fails to describe a representative number of species to support the term “an associating agent.” The Examiner continues that the specification provides only one example of an associating agent, i.e. cysteines that are available to form disulphide bonds and concludes that one of skill in the art could not envision other types of molecules having similar functions.

Applicants respectfully traverse, as one of skill in the art could have, at the time the application was filed, in fact, envisioned other types of molecules having functions similar to cysteines that are available to form disulphide bonds, as evidenced, e.g., by the specification of the instant application. The properties required for an associating agent are set forth in detail at page 12, line 5 to page 13, line 2 of the specification. The specification further describes not only cysteine residues as associating agents, but also discloses the avidin-biotin complex as associating agents. See page 13, lines 1-2. The person skilled in the art readily would be aware of other associating agents that have the necessary properties to be associating agents in the context of the claimed invention. It is a well established principle that what is conventional or well known to one of ordinary skill in the art need not be disclosed in detail (*see* MPEP § 2163 (II.A.3.a.); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d at 1384 (Fed. Cir. 2005)) and applicants respectfully submit that nothing more is required to satisfy 35 USC 112, first paragraph.

For example, at the time of the priority date of the instant application, July 30, 2002, other “associating agents” were well known to one of skill in the art. For example, WO91/17271 disclosed a tag and a tag binding ligand as associating agents, where the tag is fused to the protein of interest and the tag binding ligand is fused to a bacteriophage coat protein. *See* WO91/17271 page 2, line 30-35. The interaction between the associating agents resulted in display of the protein of interest on the surface of a phage. *See* WO91/17271 page 3, lines 1-3. The vector disclosed in WO91/17271 is a discistronic vector encoding either a VH or a VL and a phage coat protein, thus clearly distinguishable from the present claims. *See* WO91/17271, page 8, lines 17-22. Additionally, Cramer & Suter describe the phage display of cDNA gene product

libraries utilizing a jun/fos leucine zipper as associating agents. There jun was fused to pIII phage coat protein and fos was fused to a cDNA gene product. See page 70, para. 1.

One of skill in the art at the time of the priority date could have envisioned any and all of the above representative species, which are sufficient to support the claim element “an associating agent.” Accordingly, it follow that one skilled in the art also would conclude that applicants had possession of the elements of the claimed invention at the time of filing, and that the instantly claimed invention fully complies with the requirements of 35 USC §112, first paragraph. Withdrawal of the rejection respectfully is requested.

Rejection under 35 USC §112 second paragraph.

Claims 1-19 are rejected under 35 USC §112, second paragraph, as indefinite for reciting a vector comprising nucleic acids and polypeptides. Applicants respectfully submit that amended claim submitted herein render the rejection moot and request withdrawal of the rejection.

Information Disclosure Statement

The references cited above in applicant's remarks are included in an Information Disclosure Statement (IDS) submitted concurrently herewith. The following references also are being submitted in the IDS and, in order to expedite prosecution, a brief summary of each is provided. WO 98/11241 claims a tricistronic expression vector suitable for expression of proteins in a mammalian host cell. Claims 1-3. Preferably, the cistrons comprise a VH or VH-fusion polypeptide, a VL, and a selection marker. Page 5, lines 9-13, 28-31; Page 6, lines 1-4; and Examples 4-7. Mielke, et al. 2000 discloses a tricistronic vector comprising two cDNAs and a puromycin-resistance gene. Page 2, col.2, para. 1; and Fig.1.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully submit that the application is in condition for allowance. Should the Examiner feel that there are any issues outstanding after consideration of this response, the Examiner is invited to contact the undersigned to expedite prosecution of the application.

The Commissioner is hereby authorized by this paper to charge any fees during the entire pendency of this application including fees due under 37 C.F.R. §§1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-3840.

Respectfully submitted,



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